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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

MARGARET CUMMING,

Plaintiff,

v.

PROCTER & GAMBLE
PHARMACEUTICALS, INC. AND
AVENTIS PHARMACEUTICALS, INC.,

Defendants.

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CIVIL ACTION NO. 1:08-CV-5665

ANSWER

Procter & Gamble Pharmaceuticals, Inc. ("P&G") and sanofi-aventis U.S. L.L.C.
("sanofi-aventis US"), successor in interest to Aventis Pharmaceuticals, Inc., answer Plaintiff
Margaret Cumming's ("Plaintiff") Original Complaint ("Complaint") as follows:

As a preliminary matter, P&G and sanofi-aventis US note that Plaintiff has alleged she is
a resident of Victoria, Australia, yet Plaintiff's Complaint provides few, if any, specific
allegations regarding how and where she allegedly obtained and ingested Actonel. Such events
may have transpired in Victoria, Australia, and related evidence is peculiarly within Plaintiff's

ANSWER

knowledge or control. Therefore, P&G and sanofi-aventis US expressly reserve the right to amend and/or supplement their Answer and Affirmative Defenses as discovery progresses, to seek dismissal based on the doctrine of *forum non conveniens* and/or other available grounds, and to join additional parties.

1. P&G and sanofi-aventis US admit that this is a civil action for alleged damages suffered by Plaintiff. However, P&G and sanofi-aventis US deny that Plaintiff has suffered any damages as a result of her allegedly being prescribed and her alleged ingestion of the medication Actonel.

PARTIES

2. In answer to paragraph 2 of the Complaint, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

3. In answer to paragraph 3 of the Complaint, Defendant P&G admits that it is an Ohio corporation with its principal place of business in Cincinnati, Ohio. Defendant P&G denies any remaining allegations.

4. In answer to paragraph 4 of the Complaint, Defendant sanofi-aventis US admits that it is a Delaware corporation with its principal place of business in New Jersey. Defendant sanofi-aventis US denies any remaining allegations.

5. In answer to paragraph 5 of the Complaint, P&G and sanofi-aventis US admit that they conduct business in the state of New York. P&G and sanofi-aventis US deny any remaining allegations.

JURISDICTION

6. In answer to paragraph 6 of the Complaint, P&G and sanofi-aventis US admit that jurisdiction is proper in federal court. P&G and sanofi-aventis US further admit that Plaintiff, upon information and belief, is a citizen of a foreign state, and P&G and sanofi-aventis US are citizens of different states. Although P&G and sanofi-aventis US deny Plaintiff is entitled to same, P&G and sanofi-aventis US admit that upon information and belief, the amount in controversy appears to be greater than \$75,000.

FACTUAL BACKGROUND

7. In answer to paragraph 7 of the Complaint, Defendant P&G admits that it designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis US admits that it marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis US denies the remaining allegations contained in paragraph 7.

8. In answer to paragraph 8 of the Complaint, P&G and sanofi-aventis US admit that Actonel is a brand name of risedronate sodium and that it is a prescription drug that is taken orally. P&G and sanofi-aventis US deny any remaining allegations.

9. In answer to paragraph 9 of the Complaint, P&G and sanofi-aventis US admit that Actonel was approved by the United States Food and Drug Administration ("FDA") for prevention and treatment of osteoporosis.

10. In answer to paragraph 10 of the Complaint, P&G and sanofi-aventis US deny the allegations. By way of further answer, P&G and sanofi-aventis US state that the Actonel labeling and package inserts were approved by FDA and contained appropriate and adequate

warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge.

11. P&G and sanofi-aventis US deny the allegations contained in paragraph 11.

12. The allegations in paragraph 12 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US deny the allegations contained in paragraph 12 except to respectfully refer the Court to the referenced report for its true and complete contents.

13. The allegations in paragraph 13 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

14. In answer to paragraph 14 of the Complaint, P&G and sanofi-aventis US deny the allegations. By way of further answer, P&G and sanofi-aventis US state that the Actonel labeling and package inserts were approved by FDA and contained appropriate and adequate warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge.

15. In answer to paragraph 15 of the Complaint, P&G and sanofi-aventis US state that they lack knowledge and information sufficient to form a belief regarding the truth or falsity of the allegations, and therefore deny the allegations contained therein.

16. P&G and sanofi-aventis US deny the allegations contained in paragraph 16.

17. P&G and sanofi-aventis US deny the allegations contained in paragraph 17, including all separate subparts.

FIRST CLAIM FOR RELIEF

18. P&G and sanofi-aventis US incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 17 above.

19. In answer to paragraph 19 of the Complaint, Defendant P&G admits that it designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis US admits that it marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis US denies the remaining allegations contained in paragraph 19.

20. P&G and sanofi-aventis US deny the allegations contained in paragraph 20.

21. P&G and sanofi-aventis US deny the allegations contained in paragraph 21.

22. P&G and sanofi-aventis US deny the allegations contained in paragraph 22.

23. P&G and sanofi-aventis US deny the allegations contained in paragraph 23.

24. P&G and sanofi-aventis US deny the allegations contained in paragraph 24.

SECOND CLAIM FOR RELIEF

25. P&G and sanofi-aventis US incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 17 above.

26. In answer to paragraph 26 of the Complaint, Defendant P&G admits that it designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis US admits that it marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis US denies the remaining allegations contained in paragraph 26.

27. P&G and sanofi-aventis US deny the allegations contained in paragraph 27.

28. P&G and sanofi-aventis US deny the allegations contained in paragraph 28.

29. P&G and sanofi-aventis US deny the allegations contained in paragraph 29.

THIRD CLAIM FOR RELIEF

30. P&G and sanofi-aventis US incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 17 above.

31. In answer to paragraph 31 of the Complaint, Defendant P&G admits that it designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis US admits that it marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis US denies the remaining allegations contained in paragraph 31.

32. In answer to paragraph 32 of the Complaint, P&G and sanofi-aventis US admit that they had a duty to comply with all applicable law, which they did. P&G and sanofi-aventis US deny the remaining allegations contained in paragraph 32.

33. P&G and sanofi-aventis US deny the allegations contained in paragraph 33.

34. P&G and sanofi-aventis US deny the allegations contained in paragraph 34.

35. P&G and sanofi-aventis US deny the allegations contained in paragraph 35.

FOURTH CLAIM FOR RELIEF

36. P&G and sanofi-aventis US incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 17 above.

37. P&G and sanofi-aventis US deny the allegations contained in paragraph 37.

38. In answer to paragraph 38 of the Complaint, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief regarding the truth or falsity of the allegations asserted, and therefore deny the allegations contained therein.

39. P&G and sanofi-aventis US deny the allegations contained in paragraph 39.

40. P&G and sanofi-aventis US deny the allegations contained in paragraph 40.

FIFTH CLAIM FOR RELIEF

41. P&G and sanofi-aventis US incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 17 above.

42. P&G and sanofi-aventis US deny the allegations contained in paragraph 42.

43. In answer to paragraph 43 of the Complaint, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief regarding the truth or falsity of the allegations asserted, and therefore deny the allegations contained therein.

44. P&G and sanofi-aventis US deny the allegations contained in paragraph 44.

45. P&G and sanofi-aventis US deny the allegations contained in paragraph 45.

PRAYER FOR RELIEF

46. Plaintiff's "Prayer for Relief" section of the Complaint does not contain allegations of fact and therefore no responsive pleading is required. To the extent a response is deemed necessary, P&G and sanofi-aventis US deny each and every allegation and assertion listed under the "Prayer for Relief" section of Plaintiff's Complaint and deny that Plaintiff is entitled to any of the relief requested.

AFFIRMATIVE DEFENSES

47. Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable P&G and sanofi-aventis US to determine all of their legal, contractual and equitable rights, P&G and sanofi-aventis US hereby give notice that they intend to rely upon such other defenses as may become available or appear during discovery proceedings in this case and hereby reserve the right to amend and/or supplement this answer to assert any such defense at a future time and in conformity with the Federal Rules of Civil Procedure.

FIRST AFFIRMATIVE DEFENSE

48. The Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

49. Any product for which P&G and sanofi-aventis US were responsible at the time of the occurrences or injuries alleged by Plaintiff was not defective and unreasonably dangerous in its design, manufacture, or marketing, and it was at all times reasonably safe and reasonably fit for its intended use. The warnings and instructions accompanying the product at issue in this case were legally adequate warnings and instructions.

THIRD AFFIRMATIVE DEFENSE

50. Plaintiff's claims are barred in whole or in part because P&G and sanofi-aventis US provided adequate "direction or warnings" as to the use of any of its products within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

FOURTH AFFIRMATIVE DEFENSE

51. P&G and sanofi-aventis US assert the applicability of comment k of the Restatement (Second) of Torts § 402A, which bars Plaintiff's claims in this lawsuit.

FIFTH AFFIRMATIVE DEFENSE

52. P&G and sanofi-aventis US deny that Plaintiff used any product manufactured or marketed by P&G and sanofi-aventis US as alleged in Plaintiff's Complaint.

SIXTH AFFIRMATIVE DEFENSE

53. Any and all damages alleged by Plaintiff may have been caused by misuse of the product at issue, failure to use the product properly, and/or alteration or negligent use of the product.

SEVENTH AFFIRMATIVE DEFENSE

54. If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

EIGHTH AFFIRMATIVE DEFENSE

55. The occurrences and injuries alleged by Plaintiff were caused or contributed to by the negligence, breaches of warranty, or defective products of third parties over whom P&G and sanofi-aventis US had no control and for whom they are not responsible.

NINTH AFFIRMATIVE DEFENSE

56. Plaintiff's claims may be barred by negligence and/or the contributory negligence of others, and/or by the assumption of risks, if any, inherent in the alleged use of the product at issue by Plaintiff and/or the treating physicians and/or other health care providers.

TENTH AFFIRMATIVE DEFENSE

57. If Plaintiff sustained the injuries and damages alleged in the Complaint, such injuries resulted, in whole or in part, from the culpable conduct and negligence of Plaintiff and/or of third parties, not from any negligence or breach of duty by P&G and sanofi-aventis US.

ELEVENTH AFFIRMATIVE DEFENSE

58. The occurrences and injuries alleged by Plaintiff resulted from an intervening cause or a new and independent cause which was the proximate and/or producing cause and/or the sole proximate and/or sole cause of the occurrences and injuries alleged by Plaintiff. Moreover, the occurrences and injuries were caused by separate and independent events or agencies not reasonably foreseeable. Such separate and independent events or agencies destroy the causal connection, if any, between any alleged breach of legal duty on the part of P&G and sanofi-aventis US and the occurrences and injuries alleged by Plaintiff, and thereby become the immediate and/or sole cause and/or sole proximate cause of such occurrences and injuries, relieving P&G and sanofi-aventis US of liability to Plaintiff or any other parties.

TWELFTH AFFIRMATIVE DEFENSE

59. If Plaintiff sustained the injuries or incurred the expenses alleged, the same may have been caused, in whole or in part, by operation of nature or act of God.

THIRTEENTH AFFIRMATIVE DEFENSE

60. If Plaintiff sustained the injuries or incurred the expenses alleged, the same may have been caused by an idiosyncratic reaction, without any negligence, defect, or failure on the part of P&G and sanofi-aventis US.

FOURTEENTH AFFIRMATIVE DEFENSE

61. If the Plaintiff sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and unrelated medical, genetic and environmental conditions, diseases, or illnesses, subsequent medical conditions or natural courses for which P&G and sanofi-aventis US are not responsible.

FIFTEENTH AFFIRMATIVE DEFENSE

62. The Federal Food & Drug Administration (“FDA”) has implemented a comprehensive regulatory scheme governing the safety and efficacy of prescription drugs. The drug at issue in this case (the “product” or “product at issue”) was approved by FDA pursuant to such applicable statutes and regulations and, pursuant to such, could only be used pursuant to the prescription of a licensed prescriber. The labeling for the product at issue was also approved by FDA and the marketing was conducted in conformity with FDA’s rules and regulations. To the extent Plaintiff asserts claims based on P&G and sanofi-aventis US’s adherence to and compliance with applicable federal laws, regulations and rule, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

SIXTEENTH AFFIRMATIVE DEFENSE

63. Plaintiff cannot recover because the product at issue was designed and/or made in accordance with the state of the art at the relevant time.

SEVENTEENTH AFFIRMATIVE DEFENSE

64. P&G and sanofi-aventis US state that the benefits of the product at issue outweigh the risks, if any, which may be attendant to its use.

EIGHTEENTH AFFIRMATIVE DEFENSE

65. Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations.

NINETEENTH AFFIRMATIVE DEFENSE

66. Plaintiff’s claims are barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

TWENTIETH AFFIRMATIVE DEFENSE

67. To the extent Plaintiff is seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

TWENTY-FIRST AFFIRMATIVE DEFENSE

68. To the extent that Plaintiff relies upon any theory of breach of warranty, Plaintiff did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

TWENTY-SECOND AFFIRMATIVE DEFENSE

69. Actonel is a prescription pharmaceutical that was available only upon the prescription of a licensed physician, and persons other than P&G and sanofi-aventis US, including Plaintiff's treating physicians and health care personnel and institutions, stood in the position of learned intermediaries between P&G and sanofi-aventis US and Plaintiff. Any claims against P&G and sanofi-aventis US accordingly are barred in whole or in part by the learned intermediary doctrine.

TWENTY-THIRD AFFIRMATIVE DEFENSE

70. Plaintiff's claims are barred as a matter of law pursuant to Restatement (Third) of Torts §§ 2, 4, and 6.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

71. Plaintiff's claims relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First Amendment rights to petition the government.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

72. This action is more appropriately brought in Victoria, Australia, than in the United States District Court for the Southern District of New York. Therefore, P&G and sanofi-aventis US hereby assert the applicability of the doctrine of *forum non conveniens* and reserve the right to pursue a motion to dismiss based on the doctrine of *forum non conveniens* as discovery in the case proceeds. In the alternative, P&G and sanofi-aventis US reserve their rights to seek dismissal or transfer of the case on grounds of improper venue and/or inconvenient venue.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

73. To the extent Plaintiff settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, P&G and sanofi-aventis US's liability, if any, should be reduced accordingly.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

74. Plaintiff's claims are barred in whole or in part because Plaintiff has failed to mitigate the alleged damages.

JURY DEMAND

P&G and sanofi-aventis US hereby demand a trial by jury on all of Plaintiff's claims.

WHEREFORE, Defendants P&G and sanofi-aventis US pray for judgment as follows:

1. That Plaintiff take nothing by her Complaint;
2. For such other and further relief as the court may deem just and proper.

Dated: July 11, 2008

Respectfully submitted,

By: 

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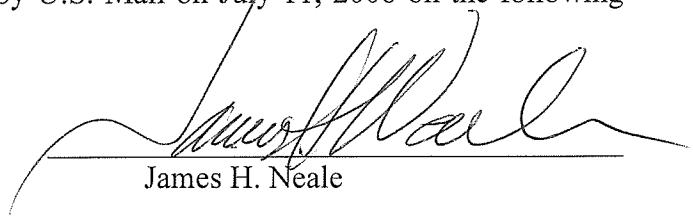
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CERTIFICATE OF SERVICE

I certify that this document was served by U.S. Mail on July 11, 2008 on the following counsel:



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